Summary of Public Comments received on the Challenge substance 2-Nitropropane (CAS 79-46-9) Draft Screening Assessment Report and Risk Management Scope for Batch 8

Overarching comments on the draft screening assessment reports for Batch 8 to be addressed as part of the Chemicals Management Plan Challenge were provided by Chemical Sensitivities Manitoba and Canadian Environmental Law Association, Dow Chemical Canada, Inuit Tapiriit Kanatami (ITK) and the European Chemicals Agency

A summary of comments and responses is included below, organized by topic:

- Persistence
- Inherent Toxicity
- Risk Management Scope
- Exposure
- Data gaps and deficiencies
- Risk Assessment Conclusion

TOPIC	COMMENT	RESPONSE
Persistence	Five of the six models suggest that 2-nitropropane is biodegradable, yet the conclusion is that 2-nitropropane is not biodegradable. It is not evident why this conclusion was made. A detailed rationale should be provided in the final assessment.	Although most of the biodegradation models predicted rapid biodegradation of 2-nitropropane, there were concerns with how these models deal with substances containing nitro groups. In contrast, there were also six experimental biodegradation studies for 2-nitropropane, all of which indicated that it is persistent in water. Therefore, the weight of evidence suggests persistence in water. Further explanation for this conclusion has been provided in the final assessment.
	The potential impacts of long-range transport need to be addressed in the report.	Further assessment indicates that 2-nitropropane undergoes rapid photolysis and therefore is not expected to be persistent in air. Consequently, long-range transport and deposition are not likely to be a concern for 2-nitropropane.
Inherent Toxicity	The ecotoxicity, in particular bioaccumulation, should be re-examined. As well, data on ecological effects in soil and air should be added to the assessment.	The experimental and modelled data both support the conclusion that 2-nitropropane does not meet the criteria for bioaccumulation potential. Therefore there is no need to re-examine ecotoxicity effects with regard to the bioaccumulation data.

		There is limited data for effects on non-aquatic organisms and a brief discussion has been added to the Screening Assessment Report. No studies have been found for effects on soil-dwelling organisms.
	Inhalation studies for carcinogenicity are needed.	The Challenge screening assessments are based on consideration of the available data. In the case of 2-nitropropane, chronic inhalation study data was available, and was used as information to support the assessment of human health risk. The information available was considered sufficient to provide the basis for a decision in the context of a screening assessment.
	There was an inconsistency in the reporting of 2-nitropropane concentration used in a 22-month study in rats.	To clarify the inconsistency of reporting of 2-nitropropane concentration used in a 22-month study from different organizations, a footnote has been added in the Screening Assessment Report to explain the cause. The footnote states: "This concentration level was converted from the reported level of 25 ppm based on the IARC conversion factor. In the Griffin study, considering the specific altitude of the experiment site (1350 m) and at 25 °C, the concentration level of 25ppm is equivalent to 78 mg/m3. The USEPA used the value of 78 mg/m3."
Proposed Risk Management	Given that it is a non-threshold carcinogen, a requirement for changes in use-pattern is not adequate as a risk management tool. The risk management focus needs to be expanded to address the volume already in commerce and its potential presence as an impurity in various products.	Products identified as containing 2-nitropropane were intended for industrial or commercial applications. The assessment shows that as a result of these uses, the exposure of the general Canadian population is expected to be negligible. Therefore, risk management is focused on keeping exposures low through application of the Significant New Activity (SNAc) provisions, requiring that any proposed new manufacture, use or import be subject to further assessment, and the potential delisting of 2-nitropropane from the food additives table, Division 16 (Food Additives) of the *Food and Drug Regulations*.
	There is no indication that efforts will be made to pursue substitution with safer alternatives, where feasible.	There is evidence that 2-nitropropane has been replaced by other alternative solvents in food packaging applications.
Risk Management	With 2-nitropropane potentially being formed in relatively large quantities by natural mechanisms, it	2-nitropropane does not meet the virtual elimination criteria set out in subsection 77(4) of CEPA 1999. Virtual elimination is not

Scope	would not be appropriate to apply the virtual elimination provisions of the *Canadian Environmental Protection Act, 1999.*	being proposed for this substance.
	Although with the Government recognizes the risk of 2-nitropropane is low from all sources, is the risk low enough to require a Future Use Notification?	The decision to use a Significant New Activity provision is to ensure we are informed of changes in use, and can assess whether increases in use or new uses can be allowed or whether additional risk management is required. It requires that additional information be provided by whoever wishes to manufacture, import or use the substance above a specified threshold. This information will allow Environment Canada and Health Canada to assess the potential risks associated with the new uses and identify whether additional risk management is required.
	Another potential risk management action for consideration would be addition to the Cosmetic Hotlist. Also, because apparently there is a single facility involved with 2-nitropropane, a Pollution Prevention Plan may be appropriate.	For a substance to be added to the Hotlist, if it is not reported as an ingredient in the Cosmetics Notification System, there must be foreseeable use (i.e., be a possible ingredient for the cosmetics industry). There are currently no plans to add 2-nitropropane to the Cosmetic Ingredient Hotlist as there are no indications that it could be used as a cosmetic ingredient for products sold in Canada. As the 2-nitropropane is incinerated at one facility reporting its use, a Pollution Prevention Plan is not being recommended at this time.
	If the objective of risk management is to reduce and or minimize exposure, why does the risk management not address tobacco smoke which is the most significant source of exposure (tobacco smoke) identified and stated in the assessment?	A number of risk management activities related to tobacco are already in place. For example, regulations have been made pursuant to the *Tobacco Act*, regarding the manufacture, sale, labelling and promotion of tobacco products.
	All the suggested risk management actions should be developed to target unacceptable risk with a Sustainable Development Objective. The actions should meet societal demands for the products involving the substance; include a safe and reliable food or product supply; ensure economics remain viable (maintain facility or product availability and affordability); and real and tangible improvements to the environment and human health.	Socio-economic factors are considered in the selection process for a regulation and/or instrument respecting preventive or control actions, and in the development of the risk management objective(s).
Exposure	The models used in the assessment of 2-	If conservative assumptions produce model results that indicate

	nitropropane are overly conservative.	risk, the exposure scenario is revised using more realistic assumptions when the data are available to carry out this refinement. However, in the case of 2-nitropropane, conservative assumptions produce model results that indicate no risk so there is no need to revise the exposure scenario.
	There is inadequate attention given to the potential effects on vulnerable populations (pregnant women, children and aboriginal populations) and occupational exposure.	The Challenge screening assessments are based on consideration of the available data. The conservative exposure scenarios used are considered to be protective of vulnerable populations in Canada, and do incorporate specific calculations for Canadians of different ages. For non-cancer endpoints, the maximum exposure of the most vulnerable population (children aged 6-8) was used for risk characterization. Hazard information obtained from occupational settings, in particular data from epidemiological investigations, is considered in the screening assessment. The information developed through the Chemicals Management Plan process may be used to inform decisions concerning additional actions to minimize exposure to workers. The Government of Canada is communicating results to appropriate occupational health and safety groups.
	Without reported releases, the amount released and media of release is unknown. It is further suggested that the NPRI reporting threshold is inadequate.	Canadian importers or manufacturers of 2-nitropropane were subject to section 71 reporting requirements, which included a requirement to disclose releases to air, land and water. The absence of reported releases supports the assertion that exposure of the general population resulting from releases to environmental media is likely to be negligible. Any party (person, government or organization) in Canada may submit a proposal to Environment Canada for changes to the National Pollutant Release Inventory (NPRI) program. Changes to the substance list result from the NPRI consultations process and may include the addition, modification or removal of substances as well as changes in the thresholds at which they must be reported under section 46 of CEPA 1999.
	Research and monitoring is needed to determine the	Although monitoring data would be beneficial in providing

	concentration in environmental media and specific imported consumer products to inform exposure estimates.	additional support for exposure assessment, in the case of 2-nitropropane, the very small release estimates made by the Ontario Ministry of the Environment, the low ambient concentrations predicted by the US Environmental Protection Agency both near and away from point sources and the small import quantities reported by Canadian companies all suggest that this substance would not be a priority for environmental monitoring. With respect to monitoring of consumer products, the principal use of 2-nitropropane as a solvent in paints and coatings might be expected to lead to consumer exposure. Although large quantities of 2-nitropropane had previously been used by the coatings industry, the shift towards coatings with a lower content of volatile organic compounds has resulted in move away from the use of this substance as a solvent. Paint and coating products identified as containing 2-nitropropane appear to be for industrial or commercial use.
	The disposal of 2-nitropropane should be researched further since there is no data available.	The Challenge screening assessments are based on consideration of the available data. As acknowledged in the report, releases from waste disposal sites are possible and could contribute to environmental concentrations. However, the available information is currently not sufficient to derive a quantitative estimate. Although this uncertainty is noted in the report, 2-nitropropane is imported in small quantities and no consumer use scenarios were identified, and it is unlikely that the disposal is contributing significantly to exposure of the general population.